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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,107	06/14/2001	Darci T. Horne	044921-5028	4972

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/880,107

Applicant(s)

HORNE ET AL.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8, 12 and 14-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9-11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of Group I, corresponding to claims 1-3, 5-7, 9-11, and 13 and genes having SEQ ID NOs: 2492, and 3847 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 3, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohmachi et al. (Journal of Hepatology, (1994), Vol. 21, pages 1012-1016).

Ohmachi et al teach a method of monitoring the progression of liver cancer and hepatocellular carcinoma in a patient (Abstract and Page 1012, Column 2, first four lines) comprising:

a) administering a pharmaceutical composition to the patient (Patients and Methods Section and Results section and Discussion Section);

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b) preparing a gene expression profile from a cell or tissue sample from the patient (Table 1 and Figures 1-2); and

c) comparing the patient gene expression profile to a gene expression from a cell population selected from normal liver cells and hepatocellular carcinoma (Table 1 and Figures 1-2).

This rejection is based on the fact that HBV DNA or the X gene can be considered as a pharmaceutical composition.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) over Ohmachi et al. (Journal of Hepatology, (1994), Vol. 21, pages 1012-1016) in view of Hillier et al. (Genbank Accession NO: N33920) (January 11, 1996) further in view of Tomita et al. (FEBS Letters, (1987), Vol. 225(NO; 1,2), pages 113-119)

Ohmachi et al teach the method of claims 3 and 7 as described above.

Ohmachi et al do not teach the liver gene having SEQ ID NO: 2492.

Hillier et al. teach the liver gene having SEQ ID NO: 2492 (Genbank Accession NO: N33920) (January 11, 1996) (a copy attached herewith).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the liver gene having SEQ ID NO: 2492 of Hillier et al. in the method of Ohmachi et al, since Ohmachi et al. states “Similarly, as these states occur during the development of hepatocellular carcinoma (HCC), any changes that occur in cellular gene expression including PSTI, are reproducibly augmented in HCCs (Page 1012, Column 2, first four lines)”. An ordinary practitioner would have been motivated to substitute and combine the liver gene having SEQ ID NO: 2492 of Hillier et al. in the method of Ohmachi et al, in order to achieve the express advantages , as noted by Ohmachi et al., of detecting any changes that occur in cellular gene expression including PSTI which are reproducibly augmented in HCCs and can naturally be used as a marker of diagnosis of HCC.

Ohmachi et al. in view of Hillier et al do not teach the gene having SEQ ID NO: 3847.

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Tomita et al. teach the gene having SEQ ID NO: 3847 (Figure 2 and Genbank Accession NO:Y00705).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the liver gene having SEQ ID NO: 3847 of Tomita et al. in the method of Ohmachi et al in view of Hillier et al, since Tomita et al suggests that the growth factors isolated from human hepatoma cells is identical with those of human PSTI of SEQ ID NO: 3847 (Page 118, third paragraph, lines 27-32). An ordinary practitioner would have been motivated to substitute and combine the liver gene having SEQ ID NO: 3847 of Tomita et al. in the method of Ohmachi et al in view of Hillier et al, in order to achieve the express advantages , as noted by Tomita et al., of detecting any changes that occur in cellular gene expression including PSTI from human hepatoma cells and which can naturally be used as a marker of diagnosis of hepatoma.

6. Claims 9-11 and 13 are rejected under 35 U.S.C. 103(a) over Ohmachi et al. (Journal of Hepatology, (1994), Vol. 21, pages 1012-1016) in view of Tomita et al. (FEBS Letters, (1987), Vol. 225(NO; 1,2), pages 113-119) further in view of Hillier et al. (Genbank Accession NO: N33920) further in view of Yeatman et al. (Nucleic Acids research, (1995), Vol. 23(19), pages 4007-4008).

Ohmachi et al. in view of Hillier et al. further in view of Tomita et al teach method of claims 1, 2, 5, and 6 as described above.

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Ohmachi et al. in view of Hillier et al. further in view of Tomita et al do not teach method of diagnosing and differentiating metastatic liver cancer from non-metastatic cells.

Yeatman et al. teach method of diagnosing and differentiating metastatic liver cancer from non-metastatic cells (Figures 1 and 2 and Page 4007, Column 1, line 1 to Column 2, line 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of diagnosing and differentiating metastatic liver cancer from non-metastatic cells of Yeatman et al. in the method of Ohmachi et al. in view of Hillier et al. further in view of Tomita et al, since Yeatman et al. states, "With this revised methodology, we were able to successfully identify a message that was overexpressed in colon cancer cells that are highly-metastatic to the liver when compared with cells that are non-metastatic (Page 4007, Column 1, last three lines of fourth paragraph to Column 2, line 2) ". An ordinary practitioner would have been motivated to substitute and combine the method of diagnosing and differentiating metastatic liver cancer from non-metastatic cells of Yeatman et al. in the method of Ohmachi et al. in view of Hillier et al. further in view of Tomita et al, in order to achieve the express advantages , as noted by Yeatman et al., of a revised methodology, which can successfully identify a message that is overexpressed in cancer cells that are highly-metastatic to the liver when compared with cells that are non-metastatic.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located In Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published In the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

Art Unit 1634,

August 1, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600